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Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations

Mallinckrodt LLC, a pharmaceutical manufacturer and one of the largest manufacturers of generic oxycodone, agreed to pay $35 million to settle allegations that it violated certain provisions of the Controlled Substances Act (CSA) that are subject to civil penalties, Attorney General Jeff Sessions of the Justice Department and Acting Administrator Chuck Rosenberg of the Drug Enforcement Administration (DEA) announced today.

This is the first settlement of its magnitude with a manufacturer of pharmaceuticals resolving nationwide claims that the company did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone in Florida and elsewhere. The settlement also addressed violations in the company's manufacturing batch records at its plant in Hobart, New York. Both sets of alleged violations impact accountability for controlled substances, and the compliance terms going forward are designed to help protect against diversion of these substances at critical links in the controlled substance supply chain.

"In the midst of one of the worst drug abuse crises in American history, the Department of Justice has the responsibility to ensure that our drug laws are being enforced and to protect the American people," said Attorney General Sessions. "Part of that mission is holding drug manufacturers accountable for their actions. Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. Thanks to the hard work of our attorneys and law enforcement, Mallinckrodt has agreed to do everything they can to help us identify suspicious orders in the future. And as a result of today's settlement, we are sending a clear message to drug companies: this Department of Justice will hold you accountable for your legal obligations and we will enforce our laws. I believe that will prevent drug abuse, prevent new addictions from starting, and ultimately save lives."

"Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands," said DEA Acting Administrator Chuck Rosenberg. "When they violate their legal obligations, we will hold them accountable."

The government alleged that Mallinckrodt failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances – orders that are unusual in their frequency, size, or other patterns. From 2008 until 2011, the U.S. alleged, Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders. Through its investigation, the government learned that manufacturers of pharmaceuticals offer discounts, known as "chargebacks," based on sales to certain downstream customers. Distributors provide information on the downstream customer purchases to obtain the discount. The groundbreaking nature of the settlement involves requiring a manufacturer to utilize chargeback and similar data to monitor and report to DEA suspicious sales of its oxycodone at the next level in the supply chain, typically sales from distributors to independent and small chain pharmacy and pain clinic customers.

The government also alleged that Mallinckrodt violated record keeping requirements at its manufacturing facility in upstate New York. Among other things, these violations created discrepancies between the actual number of tablets manufactured in a batch and the number of tablets Mallinckrodt reported on its records. Accurate reconciliation of records at the manufacturing stage is a critical first step in ensuring that controlled substances are accounted for properly through the supply chain.

In addition to the significant monetary penalty, this settlement includes a groundbreaking parallel agreement with the DEA, as a result of which the company will analyze data it collects on orders from customers down the supply chain to identify suspicious sales. The resolution advances the DEA's position that controlled substance manufacturers need to go beyond "know your customer" to use otherwise available company data to "know your customer's customer" to protect these potentially dangerous pharmaceuticals from getting into the wrong hands. DEA's Memorandum of Agreement with Mallinckrodt also sets forth specific procedures it will undertake to ensure the accuracy of batch records and protect loss of raw product in the manufacturing process.

By entering into these agreements, elements of which Mallinckrodt is already implementing, the company is becoming part of the solution to this public health epidemic.

This lengthy investigation was led by DEA's Detroit Field Division on the suspicious order issues and the New York Field Division on the manufacturing record keeping issues.

U.S. Attorneys' Offices for the Eastern District of Michigan and the Northern District of New York, along with DEA Office of Chief Counsel and Diversion Control Division, led the civil settlement negotiations. The Criminal Division's Narcotic and Dangerous Drug Section (NDDS) also coordinated and assisted in negotiating the settlement.

Topic(s):
Opioids
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